

Genetic research is the study of inherited human traits. Recall that GINA, The Genetic Information Nondiscrimination Act provides additional protections to individuals to prohibit discrimination in health coverage and employment on the basis of genetic testing designed to elicit genetic information.

The GINA statute defines ‘genetic test’ as an analysis of human DNA, RNA, chromosomes, proteins, or metabolites that detects genotypes, mutations, or chromosomal changes.

The statute further defines ‘genetic information’ as information about:

- an individual’s genetic tests (including genetic tests done as part of a research study);
- genetic tests of the individual’s family members (defined as dependents and up to and including 4th degree relatives);
- genetic tests of any fetus of an individual or family member who is a pregnant woman, and genetic tests of any embryo legally held by an individual or family member utilizing assisted reproductive technology;
- the manifestation of a disease or disorder in family members (family history);
- any request for, or receipt of, genetic services or participation in clinical research that includes genetic services (genetic testing, counseling, or education) by an individual or family member.

Genetic information does not include information about the sex or age of any individual.

When researchers design studies that use genetic tests to collect genetic information about an individual subject, the subject should have an opportunity to opt in to any genetic sub-study. This way, a subject who decides not to take part in the sub-study may still take part in the main study.

There are two methods for informing the subject of these options and obtaining their separate consent:

First, the researcher can describe the genetic sub-study in the consent document of the main study and obtain a separate signature for the genetic research.

Or, the researcher may choose to develop an entirely separate consent form for use with the genetic sub-study.

In either consent process, the researcher should be certain that the consent form contains information as to:

- how long and where the specimen and resulting genetic information will be stored
- whether the subject can withdraw the specimen and any resulting genetic information from the research study
- whether the subject will be told the results of any genetic testing
- who exercises control over the specimen and whether the specimen will be shared, and with whom
- whether the subject will obtain any financial benefits from the research
- whether there are any risks to participating in the research as well as efforts to minimize the risk, such as the GINA statute. For genetic research that involves determining whether subjects

U-MIC TRANSCRIPT

Genetic Sub-Studies

have an already manifest genetic disease or disorder, investigators and IRBs may wish to consider including additional language in the informed consent document indicating that GINA does not prohibit discrimination on the basis of an already manifest genetic disease or disorder.

For more information on genetic sub-studies and informed consent of subjects, contact the IRBMED.

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